Risk Evaluation and Risk Management under TSCA Section 6

Household and Commercial Products Association

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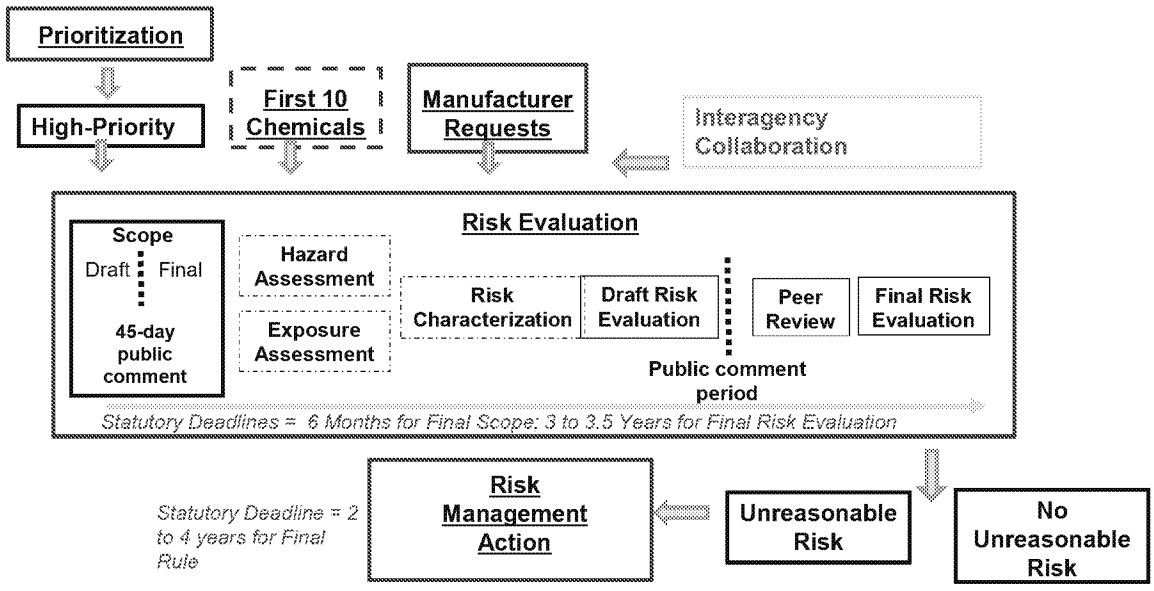
Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for Methylene Chloride, 1-Bromopropane, and HBCD
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 to 3.5 years

Risk Evaluation Process and Timeline



Overview of Risk Evaluation for Methylene Chloride

- Final risk evaluation published June 24, 2020
- EPA determined that 47 of the 53 conditions of use of methylene chloride present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
  - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute (central nervous system) and chronic (liver) inhalation and dermal exposure to methylene chloride

Overview of Risk Evaluation for 1-Bromopropane

- Final risk evaluation published August 11, 2020
- EPA determined that 16 of the 25 conditions of use of 1-BP present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Workers and occupational non-users (ONUs) during occupational exposures
  - Consumers and bystanders during exposures to consumer uses
- EPA's risk evaluation identified unreasonable risks for cancer and non-cancer adverse effects from acute and chronic inhalation and dermal exposure to 1-BP using developmental toxicity (post-implantation loss in animal studies) as the most sensitive endpoint

Overview of Risk Evaluation for HBCD

- Final risk evaluation published September 25, 2020
- EPA determined that six conditions of use of HBCD present an unreasonable risk of injury to health and/or the environment
- EPA's risk evaluation identified unreasonable risks to aquatic organisms from acute (reduced growth rate) and chronic (developmental effects) exposure to HBCD in surface water and sediment
  - Based on high end assumption of water flow rate
- EPA found unreasonable risks to workers and occupational non-users from acute (offspring loss) and chronic (thyroid effects) inhalation exposure to HBCD
  - Assumed construction and demolition workers do not use respirators

Remaining Chemicals with Upcoming Risk Evaluations

- Asbestos
- Carbon tetrachloride
- 1,4-dioxane
- NMP
- Perchloroethylene
- Pigment violet 29
- TCE

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes

- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use.
  - These authorities allow the EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers.

Examples of Regulatory Options

- Provide a prominent label securely attached to import container or product with specific directions, limitations, and precautions, or that describes the health endpoints
- Prohibit importing, processing, and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls and PPE at occupational sites
- Require importers, processors, and distributors to maintain ordinary business records
- Require importers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)

Examples of Regulatory Options

- Require monitoring of exposures in occupational settings
- Require a hazard communication program to educate workers on label directions, warnings, etc.
- Redesign import containers to prevent release to the environment
- Require engineering controls or equipment to contain releases to outside air from facilities that import, process, or recycle
- Require work practices that reduce dust emissions at construction and demolition sites
- Prohibit or regulate manner of commercial disposal

TSCA Section 6(c)

- In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:
- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
  - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives

Complex Consumer and Durable Goods—Section 6(c)(2)

- EPA shall exempt replacement parts for complex durable goods and complex consumer goods designed prior to publication of the risk management rule from TSCA section 6(a) unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation, to the general population or to an identified potentially exposed or susceptible subpopulation
- "Complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace
- "Complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use

Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs

Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including avoiding release to the environment, current work practices, engineering, and administrative controls
- Information on essential uses and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- Methylene chloride chemical lead: Ingrid Feustel, feustel.ingrid@epa.gov, 202-564-3199
- 1-bromopropane chemical lead: Ana Corado, corado.ana@epa.gov, 202-564-0140
- HBCD chemical lead: Sue Slotnick, slotnick.sue@epa.gov, 202-566-1973
- General risk management outreach: Douglas Parsons parsons.douglas@epa.gov, 202-564-0341